



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
San Francisco District

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1431 Harbor Bay Parkway  
Alameda, California 94502-7070  
Telephone: (510) 337-6700

VIA FEDERAL EXPRESS

April 15, 1999

Our Reference: 2951141

Scott H. Bradshaw, Owner  
Fish Brothers Company  
203 Taylor Way  
Blue Lake, California 95525

**WARNING LETTER**

Dear Mr. Bradshaw:

On December 3, 1998, Investigator Jennifer King of the U.S. Food and Drug Administration (FDA) conducted an inspection of your seafood processing facility. The inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110). The inspection detected deviations which constitute violations of the Federal Food, Drug, and Cosmetic Act, and related regulations for seafood processing and good manufacturing practices.

A sample of vacuum packaged smoked salmon, collected during the inspection, was analyzed for percent water phase salt by FDA. Results of the analysis by the FDA laboratory showed that the smoked salmon has an average water phase salt of 2.65 percent and 2.59 percent, by original and check analysis, respectively. To control *Clostridium botulinum* toxin formation in a vacuum packaged smoked fish or smoke-flavored fish, the guideline for water phase salt is 3.5 percent or higher. Water phase salt below 3.5 percent would not provide a preventive control for *C. botulinum* toxin formation in a refrigerated, vacuum packaged, smoked fish or smoke-flavored fish product. The sample test results reveal that your firm does not have adequate controls to prevent *Clostridium botulinum* toxin formation in a vacuum packaged smoked fish or

smoke-flavored fish. While results of water phase salt on previous lots of smoked salmon, tested by [REDACTED] and by your firm, were above 3.5 percent, the significantly lower level found by the FDA Seattle district laboratory demonstrates that your firm has not adequately established a process that will consistently provide a finished product with a water phase salt content of 3.5 percent or higher. Processors must document that the recipe utilized in brining as a critical limit consistently results in the desired water phase salt (21 CFR 123.16).

Other HACCP deviations were also observed during the inspection and were listed on Form FDA 483 and discussed with you.

Your firm is not adequately monitoring and recording relevant sanitation practices and procedures (21 CFR 123.11(c)). For example, sanitation monitoring for the condition and cleanliness of food contact surfaces, prevention of cross contamination, and maintenance of hand washing and toilet facilities are recorded only once a month on a Sanitation and Corrective Action form.

Vacuum packaged, hot smoked salmon processed in your facility under these conditions are adulterated within the meaning of Section 402(a)(4) of the Act in that they were prepared, packed, or held under insanitary conditions whereby they may become contaminated with filth, or whereby they may be rendered injurious to health. Adulterated foods are subject to seizure as authorized by Section 304 of the Act. Adulteration of food while held for sale after receipt in interstate commerce, is prohibited by Section 301(k).

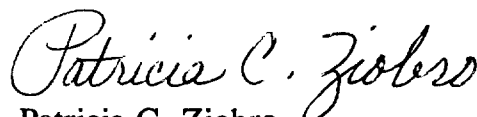
And in addition to the violations mentioned above, there are other HACCP deviations which should be brought to your attention. Monitoring records are not being reviewed weekly (21 CFR 123.8(a)(3)). For example, the Albacore Temperature Chart, Salmon Brining Log, and Salmon Smoking Recording Chart which are used as HACCP monitoring records do not have weekly verification signatures and dates for the month of November 1998. Also, your HACCP plan for hot smoked fish and monitoring records do not have the name and location of the processor (21 CFR 123.9(a)).

You must immediately take appropriate steps to correct the violations at your facility. Failure to correct the violations may result in legal sanctions such as seizure and/or injunction without further notice.

Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have instituted to correct these violations, including an explanation of

each step being taken to prevent recurrence of these violations. Please include in your response documentation to show that the parameters established in your process controls for smoked fish were the result of a scientific study. Please direct your response to Ms. Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795; FAX: 510-337-6707).

Sincerely,

A handwritten signature in cursive script that reads "Patricia C. Ziobro".

Patricia C. Ziobro  
District Director  
San Francisco District

cc: Seth P. Meynell, Production Manager